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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,322	04/23/2001	Long Y. Chiang	06897-006001	4062
26161	7590	10/22/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 10/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,322

Applicant(s)

CHIANG, LONG Y.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-7-04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of amendment and response dated 6-7-04 is acknowledged.

Claims 1-21 are pending.

Response to Arguments

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the growth of tumor cells in a tumor site by administering sulfobutylated hexadecaniline, does not reasonably provide enablement for all the oligoaniline derivatives that are within the scope of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

RESPONSE: Applicants argue that instant invention is not complex because instant claims are amended to remove from claim 1 the groups "H and CH₂-CO-NH₂" assigned to A, and the groups "-SH, -CONH₂, and -OCH₃" assigned to D, which have improved water solubility and enhanced bioavailability. Applicants also argue that instant compounds encompassed by claim 1 are not overly broad because the moieties are only limited to hydrophilic groups that possess the above characteristics of enhanced solubility and bioavailability; and that all the oligoanilines claimed can be used to inhibit the growth of tumor cells by generating oxygen free radicals. Applicants' arguments have been considered but not found persuasive because in the instant case, even though claimed breadth of compounds are capable to generate free radicals due to oligoaniline moieties, the encompassed compounds are different from each other in their structure that one of an ordinary skill in the art would have to perform undue experimentation to test each of the compounds that fall in this category in their

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ability to bind all kinds of tumor cells, generate free radicals to the extent that all kinds of tumor cells or all types or degrees of tumor cells are effectively inhibited. Further, applicants have not established a rationale to show to one of an ordinary skill in the art that claimed oligoanilines could generate oxygen free radicals specifically in tumor cells and not in the normal cells surrounding the tumor cells. One of an ordinary skill in the art would not readily envision the method of inhibiting tumor cells that are metastatic. With respect to the argument regarding the in vitro and in vivo data, applicants have not shown if murine sarcoma cells are a prototype and representative of all types of tumors known to-date. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. For the reasons set forth supra it appears that undue experimentation would be required of one skilled in the art to practice the claimed invention using the guidance provided in the instant specification.

Applicant's arguments with respect to rejection of claims 18-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al (Macromolecules 1994, submitted on IDS).

Nguyen et al teach polyaniline polymers that have high electrical conductivity and are highly water-soluble. The monomers that make up oligoaniline polymers are described in col. 2 of page 3625. Particularly, compounds of formula III read on the claimed compounds (sulfobutylated aniline polymers). On page 3626, col. 1, Nguyen teaches preparing the soluble aniline polymers not just in water, but in dispersants, which meet the claimed carrier. Instant claims recite $m=2-6$. While Nguyen et al does not specifically teach the length of the polymer,

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the number of aniline monomer in the teachings of Nguyen range from 1 to 49 (formula in col. 2, page 3625). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare sulfonylated aniline polymers having a desired chain by routine optimization, without losing the electrical conductivity and water solubility of the compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM to 6.30 PM Monday through Friday, except alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala

Examiner

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October 19, 2004

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